

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Case No. 11-cv-1389-WJM-KLM

GENETIC TECHNOLOGIES LIMITED,

Plaintiff,

v.

AGILENT TECHNOLOGIES, INC., a Delaware corporation;
BRISTOL-MYERS SQUIBB COMPANY, a Delaware corporation;
EUROFINS STA LABORATORIES, INC., a Colorado corporation;
GENESEEEK, INC., a Nebraska corporation;
GLAXOSMITHKLINE LLC, a Delaware corporation;
HOLOGIC, INC., a Delaware corporation;
MERIAL L.L.C., a Delaware corporation;
PFIZER INC., a Delaware corporation; and
454 LIFE SCIENCES CORPORATION, a Delaware corporation,

Defendants.

**DEFENDANT BRISTOL-MYERS SQUIBB COMPANY'S
ANSWER TO PLAINTIFF GENETIC TECHNOLOGIES LIMITED'S FIRST
AMENDED COMPLAINT WITH JURY DEMAND AND COUNTERCLAIMS**

Defendant Bristol-Myers Squibb Company ("BMS") responds to the First Amended Complaint With Jury Demand of Plaintiff Genetic Technologies Limited ("GTG") (the "Complaint") as follows:

FIRST DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

BMS responds to the numbered allegations of the Complaint as follows:

I. THE PARTIES

1. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

2. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

3. BMS admits that it is a corporation organized and existing under the laws of the state of Delaware and that it has a principal place of business located at 345 Park Avenue, New York, New York 10154. BMS also admits that it can be served with process through its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Otherwise, denies.

4. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

5. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

6. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

7. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

8. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

9. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

10. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

II. JURISDICTION AND VENUE

11. Paragraph 11 contains conclusions of law to which no response is required. BMS, however, does not contest that federal district courts have exclusive jurisdiction over actions for patent infringement pursuant to 28 U.S.C. § 1338(a). Otherwise, denies.

12. Paragraph 12 contains conclusions of law to which no response is required. BMS, however, does not contest that this Court has jurisdiction over the subject matter of patent infringement actions pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. Paragraph 13 contains conclusions of law to which no response is required. BMS denies that this Court is an appropriate venue because neither the parties nor the claims against BMS have any connection to Colorado. Thus, the claims against BMS should be transferred to a more convenient forum pursuant to 28 U.S.C. § 1404.

14. Paragraph 14 contains conclusions of law to which no response is required. BMS does not contest personal jurisdiction in this Court for purposes of this case. BMS denies that this Court is an appropriate venue because neither the parties nor the claims against BMS have any connection to Colorado. Thus, the claims against BMS should be transferred to a more convenient forum pursuant to 28 U.S.C. § 1404. Otherwise, denies.

III. THE PATENT-IN-SUIT

15. Paragraph 15 contains conclusions of law to which no response is required. BMS admits that the 179 patent states on its face that it was issued by the United States Patent and Trademark Office on March 18, 1997. BMS further admits that Exhibit A to the Complaint appears to be a copy of the 179 patent. Otherwise, denies.

16. Paragraph 16 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 16. Otherwise, denies.

17. Paragraph 17 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies the allegations. The 179 patent speaks for itself as to form, content, and legal effect.

18. BMS admits that the Abstract of the 179 patent contains the quoted language in Paragraph 18. To the extent that the allegations of paragraph 18 attempt to characterize the 179 patent, BMS denies those allegations. The 179 patent speaks for itself as to form, content, and legal effect.

19. Paragraph 19 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies those allegations. BMS admits that claims 1 and 26 of the 179 patent read as stated in this paragraph. To the extent that the allegations of paragraph 19 attempt to characterize the 179 patent or its claims, BMS denies those allegations. The 179 patent speaks for itself as to form, content, and legal effect.

20. Paragraph 20 of the Complaint contains conclusions of law to which no response is required. BMS admits that 35 U.S.C. § 282 provides, among other things, that a “patent shall be presumed valid.” Otherwise, denies.

21. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

22. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

23. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

24. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

25. Paragraph 25 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations. BMS admits that Exhibit B to the Complaint appears to be a copy of an Ex Parte Reexamination Certificate relating to the 179 patent dated February 4, 2010. BMS further states that the document speaks for itself as to form, content, and legal effect.

26. Paragraph 26 of the Complaint contains conclusions of law to which no response is required. BMS admits that the 179 patent has expired but is without knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore denies those allegations.

IV. DEFENDANTS' INFRINGEMENT

27. BMS denies the allegations of this paragraph as applied to BMS. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations with respect to other defendants in this paragraph, and therefore denies those allegations.

A. AGILENT

28. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

29. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

30. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

31. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

32. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

33. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

B. BRISTOL-MYERS

34. Because it is unclear what is meant by “actively engaged in pharmacogenetics” in the first sentence of paragraph 34, BMS is without knowledge or information sufficient to form a belief about the truth of that allegation, and therefore denies the allegation. Without more specificity as to the source of the quoted language in paragraph 34, BMS is without knowledge or information sufficient to form a belief about the truth of those allegations, and therefore denies those allegations. BMS further states that the allegations in quotes in paragraph 34 appear to be excerpts from several different sections of BMS’s company website even though the block quote suggests a single source. To the extent these allegations are excerpts from BMS’s website, those documents speak for themselves as to form and content. Otherwise, denies.

35. BMS admits it is a member of the Industry Pharmacogenomics Working Group. BMS also admits that the website for the Industry Pharmacogenomics Working Group states that it is “a voluntary and informal association of pharmaceutical companies engaged in research in the science of pharmacogenomics”. BMS admits that it is identified as a “member” of The SNP Consortium on a website that purports to contain information relating to the Human Genome

Project, *i.e.*, www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml. BMS further admits that the language quoted in paragraph 35 is also contained on this website. That website speaks for itself as to form and content. Otherwise, denies.

36. Because it is unclear what is meant by “actively advocated pharmacogenetic research” in the first sentence of paragraph 36, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in that sentence, and therefore denies the allegations. It is unclear what “studies” are being referred to in the second sentence of paragraph 36. Without more specificity, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in the second sentence of paragraph 36, and therefore denies those allegations.

37. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in the first sentence of paragraph 37, and therefore denies those allegations. The second sentence of paragraph 37 contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies those allegations. To the extent that the second sentence of paragraph 37 is deemed to state factual allegations or mixed allegations of law and fact, BMS is without knowledge or information sufficient to form a belief about the truth of those allegations, and therefore denies them. With respect to the third sentence of paragraph 37, BMS admits that there was a revision to the label for Coumadin[®] in 2007, and there were two revisions to the label for Plavix[®] in 2009. To the extent that the allegations of the third sentence of paragraph 37 attempt to characterize the content of the labels, the labels speak for themselves as to form and content, and BMS therefore denies the allegations.

38. BMS admits that Coumadin[®] is sold commercially in the United States, that its active ingredient is warfarin sodium, and that it is distributed by BMS. BMS is without

knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 38, and therefore denies them.

39. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 39, and therefore denies them.

40. BMS admits that the package insert in 2007 for Coumadin[®] refers to the -1639 A>G mutation. To the extent that the allegations of paragraph 40 attempt to characterize the package insert, BMS denies those allegations. The package insert speaks for itself as to form and content. BMS is without knowledge or information sufficient to form a belief about the remaining allegations of paragraph 40, and therefore denies them.

41. BMS admits there was a revision to the Coumadin[®] label in September 2007. BMS is without knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 41, and therefore denies them.

42. The first sentence of paragraph 42 contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies the allegations. To the extent that the first sentence of paragraph 42 is deemed to state factual allegations or mixed allegations of law and fact, BMS is without knowledge or information sufficient to form a belief about the truth of those allegations, and therefore denies them. The second sentence of paragraph 42 contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies those allegations.

43. BMS denies the allegations in the first sentence of paragraph 43. BMS states that it is unclear what studies are being referred to in paragraph 43, but admits that it is aware of studies concerning the CYP2C19*17 mutation. To the extent that the allegations of paragraph 43 attempt to characterize those studies or BMS's role with respect to them, those studies speak

for themselves as to form and content, and BMS therefore denies those allegations. Otherwise, denies.

44. BMS admits that Plavix[®] is commercially available in the United States, that BMS reported \$6.666 billion in net sales associated with Plavix[®] in 2010, and that Plavix[®] is co-promoted by BMS and Sanofi-aventis. Otherwise, denies.

45. BMS admits that on March 12, 2009, the FDA issued a press release concerning Plavix[®] and the liver enzyme, CY2C19. To the extent that the allegations of the first sentence of paragraph 45 attempt to characterize that FDA press release, BMS denies those allegations. The press release speaks for itself as to form and content. With respect to the second sentence of paragraph 45, to the extent the allegations attempt to characterize the package insert for Plavix[®], that document speaks for itself as to form and content, and therefore BMS denies the allegations. BMS is without knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 45, and therefore denies them.

46. The allegations of paragraph 46 contain conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies the allegations. To the extent that the allegations of paragraph 46 are deemed to state factual allegations or mixed allegations of law and fact, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations, and therefore denies them.

47. The first sentence of paragraph 47 contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies the allegations. BMS is without knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 47, and therefore denies them.

48. It is unclear what study is being referred to in paragraph 48 as no source publication is cited. Thus, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations. To the extent that the referenced study is Ranade et al., Genetic analysis implicates resistin in HIV lipodystrophy, AIDS 2008, 22:1561–1568, that publication speaks for itself as to form and content.

49. It is unclear what study is being referred to in paragraph 49 as no source publication is cited. Thus, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations. To the extent that the referenced study is Zhang et al., Characterization of the UDP Glucuronosyltransferase Activity of Human Liver Microsomes Genotyped for the UGT1A1*28 Polymorphism, Drug Metabolism and Disposition, 35:2270–2280 (2007), that publication speaks for itself as to form and content.

50. It is unclear what study is being referred to in paragraph 50 as no source publication is cited. Thus, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations. To the extent that the referenced study is Florez et al., *TCF7L2* Polymorphisms and Progression to Diabetes in the Diabetes Prevention Program, N. Engl. J. Med., 355(3): 241–250 (July 20, 2006), that publication speaks for itself as to form and content.

51. Denies.

C. ESTA

52. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

53. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

54. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

55. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

56. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

57. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

58. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

59. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

60. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

61. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

62. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

63. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

D. GENESEEK

64. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

65. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

66. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

67. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

68. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

69. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

70. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

71. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

72. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

73. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

E. GSK

74. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

75. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

76. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

77. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

78. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

79. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

80. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

81. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

82. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

83. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

84. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

85. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

86. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

87. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

F. HOLOGIC

88. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

89. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

90. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

91. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

92. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

93. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

G. MERIAL

94. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

95. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

96. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

97. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

98. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

99. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

100. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

H. PFIZER

101. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

102. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

103. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

104. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

105. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

106. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

107. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

108. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

109. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

110. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

111. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

112. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

113. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

114. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

115. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

116. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

I. 454

117. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

118. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

119. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

120. BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

V. FIRST CLAIM FOR RELIEF
(Patent Infringement by Agilent – U.S. Patent No. 5,612,179)

121. BMS incorporates by reference its responses to paragraphs 1-120 as though fully set forth herein.

122. Paragraph 122 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

123. Paragraph 123 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

124. Paragraph 124 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

125. Paragraph 125 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or

information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

VI. SECOND CLAIM FOR RELIEF
(Patent Infringement by Bristol-Myers – U.S. Patent No. 5,612,179)

126. BMS incorporates by reference its responses to paragraphs 1-125 as though fully set forth herein.

127. Paragraph 127 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies those allegations.

128. Paragraph 128 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies those allegations.

129. Paragraph 129 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS denies those allegations.

VII. THIRD CLAIM FOR RELIEF
(Patent Infringement by ESTA – U.S. Patent No. 5,612,179)

130. BMS incorporates by reference its responses to paragraphs 1-129 as though fully set forth herein.

131. Paragraph 131 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

132. Paragraph 132 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

133. Paragraph 133 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

VIII. FOURTH CLAIM FOR RELIEF
(Patent Infringement by GeneSeek – U.S. Patent No. 5,612,179)

134. BMS incorporates by reference its responses to paragraphs 1-133 as though fully set forth herein.

135. Paragraph 135 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

136. Paragraph 136 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

IX. FIFTH CLAIM FOR RELIEF
(Patent Infringement by GSK – U.S. Patent No. 5,612,179)

137. BMS incorporates by reference its responses to paragraphs 1-136 as though fully set forth herein.

138. Paragraph 138 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

139. Paragraph 139 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

140. Paragraph 140 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

141. Paragraph 141 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

X. SIXTH CLAIM FOR RELIEF
(Patent Infringement by Hologic – U.S. Patent No. 5,612,179)

142. BMS incorporates by reference its responses to paragraphs 1-141 as though fully set forth herein.

143. Paragraph 143 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

144. Paragraph 144 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

145. Paragraph 145 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

XI. SEVENTH CLAIM FOR RELIEF
(Patent Infringement by Merial – U.S. Patent No. 5,612,179)

146. BMS incorporates by reference its responses to paragraphs 1-145 as though fully set forth herein.

147. Paragraph 147 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

148. Paragraph 148 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

149. Paragraph 149 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

150. Paragraph 150 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

XII. EIGHTH CLAIM FOR RELIEF
(Patent Infringement by Pfizer – U.S. Patent No. 5,612,179)

151. BMS incorporates by reference its responses to paragraphs 1-150 as though fully set forth herein.

152. Paragraph 152 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

153. Paragraph 153 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

154. Paragraph 154 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

155. Paragraph 155 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

XIII. NINTH CLAIM FOR RELIEF
(Patent Infringement by 454 – U.S. Patent No. 5,612,179)

156. BMS incorporates by reference its responses to paragraphs 1-155 as though fully set forth herein.

157. Paragraph 157 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

158. Paragraph 158 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

159. Paragraph 159 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

160. Paragraph 160 of the Complaint contains conclusions of law to which no response is required. To the extent a response is deemed required, BMS is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies those allegations.

XIV. JURY DEMAND

As set forth in the Counterclaims below, BMS demands a trial by jury on all issues so triable.

XV. PRAYER FOR RELIEF

BMS denies that Plaintiff is entitled to any relief whatsoever.

THIRD DEFENSE

BMS denies each allegation not specifically admitted.

FOURTH DEFENSE

Plaintiff is not entitled to any relief against BMS because BMS has not and is not infringing (either directly, by inducement, or contributorily) any valid and enforceable claim of the 179 patent, nor is it doing so willfully.

FIFTH DEFENSE

The claims of the 179 patent are invalid for failing to meet one or more of the requisite conditions for patentability specified by 35 U.S.C. § 101 *et seq.*

SIXTH DEFENSE

The alleged conduct by BMS is protected, in whole or in part, under 35 U.S.C. § 271(e)(1).

SEVENTH DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted, including but not limited to, its claim for willful infringement.

EIGHTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by laches, estoppel, and/or waiver.

NINTH DEFENSE

Plaintiff's claims against BMS are improperly joined in this action.

TENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrines of res judicata and/or collateral estoppel.

ELEVENTH DEFENSE

Plaintiff's claims may be exhausted and/or satisfied, in whole or in part, to the extent there is an applicable license.

COUNTERCLAIMS

Counterclaim Plaintiff BMS alleges as follows:

PARTIES AND JURISDICTION

1. BMS is organized and existing under the laws of the State of Delaware and has a place of business at 345 Park Avenue, New York, New York 10154.

2. Plaintiff GTG states in the First Amended Complaint that it is an Australian corporation with a place of business in Victoria, Australia.

3. This Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, and 2201.

FACTS

4. Plaintiff has sued BMS, among others, claiming that GTG is the owner of the 179 patent and accusing BMS of infringing one or more claims of that patent.

5. The accusations by GTG give rise to a case or controversy within the jurisdiction of this Court, pursuant to 28 U.S.C. §§ 2201 and 2202.

COUNT I – NON-INFRINGEMENT OF THE 179 PATENT

6. BMS repeats and realleges the allegations set forth in paragraphs 1 through 5 of the Counterclaims, above, as if fully set forth herein.

7. BMS has not infringed, and is not infringing, whether directly, contributorily, or by inducement, any valid and enforceable claim of the 179 patent.

8. BMS is entitled to a declaratory judgment that it has not infringed, and is not infringing, the 179 patent.

COUNT II – INVALIDITY OF THE 179 PATENT

9. BMS repeats and realleges the allegations set forth in paragraphs 1 through 8 of the Counterclaims, above, as if fully set forth herein.

10. The 179 patent is invalid for failure to comply with the conditions for patentability set forth in 35 U.S.C. § 101 *et seq.*

11. BMS is entitled to a declaratory judgment that the 179 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, BMS prays for entry of judgment in its favor and against plaintiff on BMS's counterclaims as follows:

- A. Declaring that BMS does not infringe any claims of the 179 patent;
- B. Declaring that all claims of the 179 patent are invalid;
- C. Finding that this is an exceptional case under 35 U.S.C. § 285 and awarding BMS the costs and expenses of this litigation, including reasonable attorneys' fees and disbursements; and
- D. Awarding BMS such other relief as is just and proper.

DEMAND FOR JURY TRIAL

Defendant and Counterclaim Plaintiff BMS demands a trial by jury on all issues so triable.

Dated: October 3, 2011

s/Tracey C. Allen

Tracey C. Allen

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Attorneys for Defendant

BRISTOL-MYERS SQUIBB COMPANY

Certificate of Service

I hereby certify that on October 3, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following e-mail addresses:

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s/Tracey C. Allen

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